IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: AVANDIA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	MDL NO. 1871 07-MD-1871
THIS DOCUMENT RELATES TO: All Third Party Payor Actions	:	

MEMORANDUM OF GLAXOSMITHKLINE LLC IN OPPOSITION TO PLAINTIFFS' MOTION APPEALING THE TWENTY-FIFTH REPORT AND RECOMMENDATION OF THE SPECIAL MASTER AS TO A PROPOSED CASE MANAGEMENT ORDER FOR ALL THIRD PARTY PAYOR ACTIONS

I. INTRODUCTION

The Court should affirm the Special Master's Report and Recommendation, which reflects full consideration of the parties' extensive briefing and arguments on these discovery issues, and enter Case Management Order No. 1 ("CMO No. 1"). *See* Report and Recommendation at 4-5 (explaining the extensive consideration given by the Special Master to the CMO).

CMO No. 1 contemplates an initial discovery phase focused on two important threshold issues. **First**, whether the doctrine of federal preemption bars the claims of the four named payors (the "TPPs"). The TPPs' claims are premised on Avandia's alleged increased risk of heart attack compared to older, cheaper diabetes medications.[1] But this premise has been eviscerated by the FDA. In 2013, after the TPPs filed these actions, the FDA determined that Avandia does *not* increase cardiovascular risk compared to older diabetes drugs and required

[1] Plaintiffs allege that GSK failed "to adequately warn consumers, Third-Party Payors, prescribing doctors, and the medical and healthcare community that the use of Avandia creates a roughly 50% greater risk of heart attack and heart disease-related death." Second Am. Class Action Compl. of Allied Servs. Div. Welfare Fund ¶ 8.

GSK to revise the Avandia label to reflect this determination.[2] The FDA has also removed the restrictions on patient access to Avandia (known as the REMS program) that it imposed in 2010.[3] CMO No. 1 contemplates that GSK will file its preemption motion and produce relevant regulatory documents by mid-May. GSK has completed production of the regulatory documents ahead of schedule. *See* CMO No. 1 at 2 (requiring production by May 10).

Second, the CMO provides for the TPPs to support the claim that they were injured as a result of GSK's alleged misrepresentations to them about the cardiovascular safety of Avandia. *See* CMO No. 1 at 2 (requiring TPPs to produce Rule 30(b)(6) witnesses, and documents on Sch. A). The TPPs claim that misrepresentations by GSK caused them to pay for Avandia for their beneficiaries, and that they would have paid for cheaper, safer drugs had GSK disclosed the alleged truth about Avandia. The discovery described in the CMO is relevant to the central allegations the TPPs have made in this case, and the TPPs should provide it early on in this litigation. This discovery from the TPPs is particularly important here, as GSK has not located in its own files any communications between GSK and these four TPPs, and thus it is unclear what representations, if any, were made to the named TPPs.

Further, as this Court has already acknowledged, it will be difficult for these TPPs to prove causation if they failed to remove Avandia from or even restrict it on the formulary once the alleged truth was known. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, No. 07-md-1871, 2013 U.S. Dist. LEXIS 152726, at *28 (E.D. Pa. Oct. 23, 2013).

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[2] Memorandum from K. Mahoney (FDA) to C. Rosebraugh (FDA), Nov. 19, 2013 at 20 (Exhibit A); Nov. 25, 2013 letter from A. Egan (FDA) to M. Kreider (GSK) at 2 (Exhibit B).

[3] FDA Drug Safety Communication: FDA eliminates the Risk Evaluation and Mitigation Strategy (REMS) for rosiglitazone-containing diabetes medicines (Dec. 16, 2015) (Exhibit C), *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/UCM477575.pdf.

Plaintiffs ***do not*** object to phasing discovery so that the court and the parties can address these important threshold issues. Rather, the TPPs object to the Special Master's CMO because it does not require GSK to produce voluminous aggregate sales data spanning 17 years relating to ***other*** payors, nor require GSK to produce numerous Rule 30(b)(6) witnesses to understand the "universe of available data." Pl. Mot. at 2-3 (document 4851).[4]

The TPPs argue that they need to understand "the universe of available data," *id*. at 12, and claim that they need aggregate data to prove their case, but fail to explain how the "universe of available data" will be used or how it will prove that they were injured by GSK, despite multiple rounds of briefing on this issue. Unlike the *Neurontin* case, where the plaintiff did not get the benefit of the bargain (as the drug was not effective for the off-label uses), here the TPPs and the Court have acknowledged that Avandia is an effective treatment for diabetes. Moreover, the data the TPPs seek cannot answer whether they relied on GSK's alleged representations regarding the safety and efficacy of Avandia and whether those representations led to increased expenditures for the TPPs. The only source of that information is the files of the TPPs.

In his Report and Recommendation, the Special Master addressed the TPPs' contention that they need national sales data to establish injury and causation for each of the named TPPs. The Special Master recognized that, (1) based on the plaintiffs' Complaints, this Court and the Third Circuit never contemplated, much less sanctioned, the use of aggregate proof in this case; and (2) the Third Circuit has never approved the use of aggregate proof to establish RICO injury and causation. Further, even if the data plaintiffs seek were relevant to class

[4] GSK uses the term "aggregate data" to refer to the material described on Schedule B of plaintiffs' proposed CMO (document 4851-2). This data is not specific to GSK or Avandia. Only third-parties like IMS collect and sell data relating to *all* drugs in a class, such as how many prescriptions were written, at what dose, by whom, how many sales calls were made by each company, how much journal advertising there was, etc.

certification later in the litigation, the Special Master noted that plaintiffs can obtain it from third party vendors.

The Special Master therefore determined that GSK need not produce the data or Rule 30(b)(6) witnesses the TPPs seek, at least in this phase in the litigation. Report and Recommendation at 11. Whether aggregate proof may have some role in this litigation in the context of class certification is not an issue the Court need decide now.

The Court should approve the Special Master's thorough and well-reasoned Report and Recommendation and enter CMO No. 1.

II. ARGUMENT

A. Plaintiffs Must Produce Individual Proof of Injury and Causation to Establish Claims of the Named TPPs

1. Plaintiffs represented they would prove their case with individual proof and the Courts' prior opinions reflect that understanding

The TPPs begin their argument for discovery of aggregate data by alleging that neither this Court nor the Third Circuit "has fully engaged the question in these cases." Pl. Mot. at 5. Nothing could be further from the truth.

Back in 2011, in denying GSK's motion to dismiss, the Court wrote:

> The Court sees the alleged chain of causation as follows: 1) the manufacturer distributes misinformation about the drug; 2) TPPs rely upon that misinformation and place Avandia on their formularies; 3) physicians rely upon that misinformation (and possibly formulary status) and prescribe the drug; and 4) TPPs pay for an excess number of prescriptions for that drug.

In re Avandia Mktg., Sales Practices & Prods. Liab. Litig., 2013 U.S. Dist. LEXIS 152726, at *28-29. The Court noted that the TPPs alleged that

> doctors are more likely to prescribe drugs which are included on a patient's insurer's formulary. Absent GSK's conduct, Plaintiffs allege, many patients would have been prescribed Metformin, another effective medication for diabetes treatment, which

> Plaintiffs claim is significantly cheaper and carries less risk than Avandia. The TPPs would then have covered the cost of prescriptions for a less expensive drug, at substantial savings to them.

Id. at *18-19.

The Court recognized that because the TPPs did not act to remove Avandia from their formularies or even restrict coverage of Avandia in light of research published and widely publicized in 2007, these TPPs will have difficulty proving causation. *Id.* at *28.

On appeal, the TPPs stated that their "theory of causation is not based on the actions of ***other*** TPPs." Plaintiffs/Appellees' Brief in 3d Cir. in Response at 37 (emphasis added) (Exhibit D). Consistent with plaintiffs' own statement, the Court of Appeals explained plaintiffs' theory as one of an alleged fraud on the TPPs themselves: "The conduct that allegedly caused plaintiffs' injuries is the same conduct forming the basis of the RICO scheme alleged in the complaint – the misrepresentation of the heart-related risks of taking Avandia that causes TPPs and PBMs to place Avandia on the formulary." *In re Avandia Mktg*., 804 F.3d 633, 644 (3d Cir. 2015).

In short, the TPPs told this Court and the Court of Appeals that they would establish that GSK made misrepresentations to them, which caused them to prefer Avandia on their formularies, which in turn caused the TPPs to pay for more Avandia prescriptions at a higher price. The TPPs said nothing about using aggregate data relating to other payors to prove their case. *See* Report and Recommendation at 1-4.

After examining the opinions of this Court and the Third Circuit on GSK's motion to dismiss, the Special Master concluded that those opinions "evince[] an assumption that plaintiffs would have to prove these key elements of their cases through the traditional vehicle of individualized proof." *Id.* at 8. As the Special Master wrote, "both courts focused on the

individual plaintiffs' own decisions regarding placement of Avandia on their formularies." *Id*. Thus, both courts knew exactly what facts the TPPs proposed to develop to prove their case.

To establish the truth of the allegations the TPPs made that they suffered a RICO injury caused by GSK, the TPPs need to produce evidence about ***their*** conduct, and about ***their*** expenditures on Avandia. For example, they need to show that they paid for Avandia at a higher price because it was preferred on their formularies, and that, but for covering the cost of Avandia, they would have paid less for other drugs. The aggregate data will not establish these facts. In this initial phase of the litigation, the TPPs need to show an evidentiary basis for their *own* claims before advancing to class certification.

2. The Third Circuit has not approved of aggregate proof to establish RICO injury and causation, and the off-label cases plaintiffs rely on are factually different

As the Special Master correctly points out, the Third Circuit has never sanctioned the use of aggregate proof to demonstrate injury and causation in a RICO case. Indeed, the only court in the Third Circuit to consider the issue in the context of pharmaceutical litigation found aggregate proof was not appropriate in RICO cases. In *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 2:06-cv-5774, 2009 U.S. Dist. LEXIS 58900 (D.N.J. July 10, 2009), plaintiffs alleged that defendants' misrepresentations "caused doctors to write an increased number of prescriptions [and] . . . inflat[ed] the price of the Subject Drugs and caus[ed] TPPs to pay more for the[m] than they would have absent Schering's illegal sales and marketing scheme." 2009 U.S. Dist. LEXIS 58900, at *20. Plaintiffs offered to prove their theory "through expert testimony and a statistical analysis of Schering's sales data." *Id.* at *85. The court rejected this theory, concluding that "aggregate proof, in the form of increased demand, is not a viable theory for demonstrating RICO causation." *Id.* at *86 (citing *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 226 (2d Cir. 2008)).

Plaintiffs mistakenly suggest that *Schering* relied entirely on two district court cases that failed to "present[] any legal authority or analysis of the use of statistical or other aggregate evidence." Pl. Mot. at 6. In fact, *Schering* relied foremost on the Second Circuit's opinion in *McLaughlin* that analyzed the issue extensively. *See Schering* 2009 U.S. Dist. LEXIS 58900, at *86 ("[T]he Court concludes that [the] Second Circuit's causation analysis in *McLaughlin* should apply in this case."). In *McLaughlin*, the court rejected plaintiffs' offer of generalized proof that defendants' representations had caused them to overpay for light cigarettes, instead requiring individualized proof of causation and injury. *See McLaughlin*, 522 F.3d at 226-28 (explaining that generalized evidence could not account for individuals' choices in purchasing products and that "individual smokers would have incurred different losses depending on what they would have opted to do, but for defendants' misrepresentation").

Since *McLaughlin*, the Second Circuit has rejected the use of generalized proof in the pharmaceutical context. *See Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, 806 F.3d 71, 92, 97-98 (2d Cir. 2015) (rejecting plaintiffs' statistical analysis of sales, which demonstrated "mere correlation" and could not prove causation either with respect to the named plaintiffs or to each payor in the putative class); *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 135 (2d Cir. 2010) (concluding that plaintiffs' "theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof"). Here, plaintiffs ignore *Schering*'s reliance on *McLaughlin* and fail to acknowledge the line of Second Circuit cases that extensively explain why generalized proof would not be adequate.[5]

[5] Plaintiffs argue that the district court cases cited by the Special Master for the rejection of aggregate data or statistical analyses were overturned by the First Circuit's decision in *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013). Pl. Mot. at 8-9. The cases cited by the Special Master are *Kaiser Found. Health Plan, Inc. v. Pfizer, Inc. (In Re Neurontin Mktg. & Sales Practices Litig.)*, 748 F. Supp. 2d 34 (D. Mass. 2010) and

The plaintiffs rely heavily on the First Circuit's decision in *Neurontin* to make the point that other courts have allowed plaintiffs to establish injury and causation using aggregate proof, and that they should be allowed to do so here. *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21 (1st Cir. 2013) (approving use of aggregate data to show effect of off-label marketing). This decision is not binding on this Court and conflicts with opinions in this and other circuits, as noted above. Moreover, *Neurontin* is an off-label case that involved allegations that the drug did not work for certain off-label uses and that no physicians would have prescribed it for these uses had they known the truth. *See id.* at 47 (stating that the plaintiff had "staked much of its case on proving that Neurontin was ineffective for the promoted off-label uses"). There is no such claim here, and this Court has already recognized that Avandia is an effective drug for treatment of Type 2 diabetes, often used where patients have failed on other treatment. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 2013 U.S. Dist. LEXIS 152726, at *42 (dismissing plaintiffs' unjust enrichment claims because "based on the allegations before the Court, it appears that Plaintiffs have received the benefit of their bargains").

3. *Tyson Foods* Has No Relevance Here

Plaintiffs argued to the Special Master that the recent Supreme Court decision in *Tyson Foods v. Bouaphakeo*, No. 14-1146, 2016 U.S. LEXIS 2134 (Mar. 22, 2016), supported their request for nationwide data, and they appear to make the same argument here. The Special Master correctly distinguished this employment class action under the Fair Labor Standards Act. *See* Report and Recommendation at 11 n.25. The Supreme Court in *Tyson Foods* permitted use of a survey of the average time employees spent "donning and doffing" because data for each

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Guardian Life Ins. Co. of Am. v. Pfizer, Inc. (In re Neurontin Mktg. & Sales Practices Litig.), 677 F. Supp. 2d 479 (D. Mass. 2010). The Special Master clearly stated that he cited those cases not for their own holdings but because "they accurately note that many courts have rejected the use of statistical analysis in lieu of individualized evidence as proof of causation." Report and Recommendation at 9 n.20.

employee did not exist due to the employer's poor recordkeeping. *See Tyson Foods, Inc.*, 2016 U.S. LEXIS 2134, at *22 (explaining that plaintiffs used data "to fill an evidentiary gap created by the employer's failure to keep adequate records" and that "[i]f the employees had proceeded [individually], each employee likely would have had to introduce [the aggregate evidence] to prove the hours he or she worked").

Here, individualized data exists: each TPP has records of how many prescriptions it paid for and at what price. And even if a TPP does not, that is not due to any failure on GSK's part. If the employer in *Tyson Foods* had kept records of each employee's time spent donning and doffing, the expert testimony using survey data would likely not have been admitted.

Moreover, in this case, the issue is not just how much each TPP paid and when, but whether any fraud by GSK caused the TPP to prefer Avandia on its formulary or otherwise pay more for Avandia. Using aggregate proof on these issues is totally different from using a survey to determine what the average time was that an employee spent donning and doffing over a period of time.

B. The CMO Will Not "Further Delay" Discovery

Plaintiffs claim that the early production of GSK's national sales data would save "time and resources." *See* Pl. Mot. at 1, 3. The Special Master properly rejected this argument. The prior opinions of this Court and the Third Circuit support the conclusion that plaintiffs would need to prove their cases through "individual plaintiffs' reliance" and "individual plaintiffs' own decisions," and the "[t]he initial discovery that is covered by the proposed Case Management Order will provide the plaintiffs with the information necessary to litigate these issues." Report and Recommendation at 8.

The CMO correctly requires the TPPs to demonstrate that they can prove they suffered an injury caused by GSK before burdening GSK with production of aggregate data and

depositions about the data. The Special Master therefore endorsed a phased approach, and CMO No. 1 "requires the parties to assess the status of discovery after the initial discovery has been completed, and, by July 15, 2016, meet and confer regarding the need for further discovery." Report and Recommendation at 6. Thus, there will be another opportunity for the parties to meet and discuss the next phase of discovery, after this phase is completed.

As the Special Master explained, there is yet another reason why the CMO should not require GSK to produce aggregate data: the TPPs can better obtain it from a third party vendor. Only third parties collect data relating to the sales and promotion of all diabetes drugs, which is exactly what plaintiffs seek here. Plaintiffs claim that IMS Health maintains retail sales data only back to 2006, but, even if this were true, there are other third parties who collect and sell this data, such as Symphony Health Solutions.

C. Plaintiffs' Proposed Discovery Is Disproportionate Under Rule 26

The TPPs ask for expansive discovery of GSK's business with all payors, *i.e.*, payors other than these four TPPs. Plaintiffs seek invoice-level, transaction-by-transaction data on ***all*** sales of Avandia, for ***all*** payors, from January 1999 to the present. *See* Exhibit A to Pl. Mot. This data is out of proportion with the current needs of this case and, given its minimal relevance, its production would impose an undue burden. Under the Rules effective December 1, 2015, the scope of discovery is limited to "any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1).

Plaintiffs complain that the CMO "would require plaintiffs to produce their own data to GSK, but would not impose a reciprocal obligation on GSK." Pl. Mot. at 3. The burdensome obligation sought by Plaintiffs is hardly "reciprocal." Because of the relatively limited number of beneficiaries covered by each TPP, the TPPs' sales data is very likely to be

limited in scope.[6] In contrast, plaintiffs are plainly seeking widespread discovery of GSK in an effort to find some data they can use to support their claims, starting with the ***entire database*** of Avandia sales, concerning ***all*** purchasers of Avandia, from launch to the present. Pl. Mot. at 12.

D. GSK has already provided significant discovery relevant to this case

Plaintiffs complain that the CMO is "imbalance[d]" and provides for "lopsided discovery." *See* Pl. Mot. at 3. A review of the CMO shows that this is untrue. The TPPs – who brought this lawsuit – have not produced a shred of discovery to GSK, despite the fact that this litigation has been pending since 2010, and it has been six months since the Third Circuit ruled. Plaintiffs should be required to produce the documents that support the claims they have asserted and which they claim are valued at hundreds of millions of dollars. This should not be burdensome to plaintiffs. GSK has already produced millions of pages in the MDL, and in this litigation has already produced the additional discovery required under the CMO. Among other things, the CMO requires GSK to produce deposition transcripts and exhibits from the *Santa Clara* action; produce "documents reflecting communications with plaintiffs regarding Avandia"; produce documents updating the Avandia IND/NDA; file its motion for summary judgment on preemption; and provide depositions of "any GSK employee who communicated with plaintiffs."[7] *See* CMO No. 1 at 2-3.

[6] *See, e.g.*, UFCW First Am. Class Action Compl. ¶ 11 (24,000 members); J.B. Hunt Trans. Servs., Inc. Class Action Compl. ¶ 34 (21,535 members); United Benefit Fund Class Action Compl. ¶ 24 (2,500 members).

[7] GSK has already begun meeting its obligations under the CMO. On March 28, GSK produced to the TPPs the transcripts and exhibits for the 23 fact depositions taken in the *Santa Clara* case. GSK searched for documents reflecting communications with plaintiffs regarding Avandia or other type 2 diabetes medications, and informed plaintiffs on April 15 that it had located no such documents. Ahead of the deadline required by CMO No. 1, GSK has already produced approximately 10,000 documents, comprising 161,000 pages, of IND/NDA documents for Avandia, including all communications with the FDA. GSK is also preparing a motion for summary judgment based on federal preemption, and will file it by May 20, as required by the CMO.

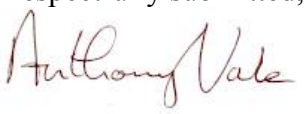
Any discussion of "burden" or "balance" in these cases must also account for GSK's massive production in the MDL, to which plaintiffs have full access. At the January status conference, plaintiffs pledged to review the MDL production in hopes of streamlining discovery in this case.[8] Yet plaintiffs make no assertion that they have actually reviewed the MDL production, and they continue to repeat that the MDL production is inadequate without suggesting that they have done anything to confirm that position. For example, plaintiffs refer to their need for physician call notes, apparently unaware that GSK has already produced approximately 1.6 million call notes in the MDL.

III. CONCLUSION

For these reasons, the Court should endorse the Special Master's Report and Recommendation and enter CMO No. 1.

Date: May 2, 2016

Respectfully submitted,



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[8] GSK promptly provided counsel for plaintiffs with all of GSK's MDL production transmittal letters to the Avandia PSC, so that plaintiffs here had additional information about what was produced. *See* Letter from J. Rickabaugh to J. Dugan and T. Sobol, Jan. 29, 2016 (Exhibit E).

CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2016, a copy of the foregoing Memorandum in Opposition to Plaintiffs' Motion Appealing the Twenty-Fifth Report and Recommendation of the Special Master as to a Proposed Case Management Order for All Third Party Payor Actions was served by electronic mail, upon plaintiffs' counsel as follows:

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